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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,190	10/21/2003	Leonard Bell	59 DIV	3662

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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	**PAPER NUMBER**
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,190	BELL, LEONARD	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a divisional of U.S. Application Serial Number 10/047,608, which claims the benefit of the filing date of provisional application 60/262,540.

Claims 1-13 are currently pending and are the subject of examination in the present Office Action.

1. In view of Applicant's amendment filed March 29, 2007 only the following ground of rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Fitch et al. (cited on form PTO-1449; Circulation (1999) 100:2499-2506).

It was previously stated: "Briefly, the claims are drawn to a method of determining the effectiveness of an anti-inflammatory compound in a patient undergoing a procedure involving cardiopulmonary bypass and comparing incidence of infarctions with control subjects wherein both groups have a blood level of creatine kinase (as CK-MB) of at least a certain level in ng/ml.

It is noted that CK-MB is found in large amounts in the heart muscle. Due to damage to the heart muscle, blood levels of CK-MB typically rise within a few hours after a heart attack, reaching a peak level before falling back to normal levels within several days. Measurement of CK-MB is one method used by practitioners to determine the occurrence of a myocardial infarction.

Fitch teaches an assay method of administering of a humanized single chain monoclonal antibody directed to human complement component C5 (h5G1.1-scFv) to subjects undergoing coronary bypass surgery (CBP) and comparing those subjects to subjects to subjects receiving a placebo. It is noted that h5G1.1-scFv is the same anti-C5 antibody exemplified in the instant specification and that the properties recited in instant claims 12 and 13 are described in the instant specification at the paragraph bridging pages 2-3 as being properties of h5G1.1-scFv. The h5G1.1-scFv antibody is a complement inhibitor [claim 9] that binds to complement component C5 [claim 10] and prevents the cleavage of C5 into C5a and C5b [claim 11] (Fitch page 2500, column 1 in particular). Fitch teaches that a post-operative measurement of CK-MB yields information on myocardial injury and that antibody-treated patients have lower CK-MB levels than placebo-treated controls (Figure 4 in particular). Fitch teaches that "[e]levated postoperative CK-MB levels are associated with an increasing incidence of postoperative ventricular regional wall abnormalities and decreased global left ventricular fraction in the early post-CABG period, which can persist up to 9 months" (page 2504, paragraph bridging columns in particular). While Fitch states that, "there does not appear to be a threshold effect," Fitch asserts that, "it is apparent that the greater the release of CK-MB, the greater the subsequent morbidity, cost, and mortality" and that, "it is likely that significant reductions in postoperative myocardial injury might be associated with improved

outcomes" (page 2504, paragraph bridging columns in particular). It is noted that Fitch is silent about patient samples comprising at least 50 ng/ml of CK-MB postoperatively, however Fitch measures CK-MB in units of IU/ml rather than in the ng/ml format used in the instant specification (Figure 4 for example). Fitch shows that the mean blood level of CK-MB in placebo controls is over 1200 IU/ml while the mean blood level in antibody treated subjects is over 600 IU/ml. The office does not have the facilities and resources to provide the factual evidence needed in order to establish the relationship between IU and ng per ml or that there is a difference between the materials, i.e., that the claims are directed to new materials and that such a difference would have been considered unexpected by one of ordinary skill in the art, that is, the claimed subject matter, if new, is unobvious. In the absence of evidence to the contrary, the burden is on the Applicant to prove that the claimed materials are different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). In other words, in the absence of evidence to the contrary, it is presumed that the CK-MB levels reported by Fitch as 600 IU/ml in the treatment group of Figure 4 is at least equivalent to the instantly recited peak levels of 50 ng/ml [claim 1], 60 ng/ml [3] 70 ng/ml [4], 80 ng/ml [5], 90 ng/ml [6], 100 ng/ml [7] or 120 ng/ml [8]. Accordingly, in the absence of evidence to the contrary, the instant invention includes the treatment of patients below a postoperative threshold level as well as those above the threshold and is therefore no different in practice than the method of Fitch. The prior art teaching anticipates the claimed invention.

Applicant's arguments filed June 26, 2006 have been fully considered but they are not persuasive.

Applicant argues that the Fitch reference is not anticipatory because Fitch does not teach the measurement of a "peak" level of CK-MB. Applicant submits that the "cumulative" measurement of CK-MB by Fitch post-operatively and Applicant's measurement of a "peak" level of CK-MB post-operatively are different in practice. While Fitch does not single out a particular peri- or post-operative measurement of CK-MB as being the "peak level," the claim requires only that the peak level be greater than 50-120 ng/ml. If subjects in the study by Fitch reach a level of greater than 50-120 ng/ml at any point during the "cumulative" measurement, then those subjects satisfy the metes and bounds of the claims as presented. It is suggested that Applicant amend the base claim to positively recite a step of measuring the peak level in a manner consistent with the disclosure of the specification."

Applicant's arguments filed March 29, 2007 have been fully considered but they are not persuasive.

Applicant has amended the claims to recite "measuring the peak level of CK-MB in the blood by analyzing intra- and post-operative blood draws" and asserts that this amendment is in line with the Examiner's suggestion in the Office Action mailed September 26, 2006. Applicant asserts that the amendment is supported by the specification as originally filed at page 9, lines 11-12. However, the specification at that location only discloses the measurement of CK-MB levels in the blood samples, not a positive step of measuring the peak level. There is no determination of a peak level supported by the relied upon passage. Fitch also 'measures' CK-MB by taking blood draw intra- and post-operatively (see page 2500, column 2 of Fitch in particular). It is suggested that the claim be further amended in accordance with page 5, line 2 of the specification as originally filed to indicate that the peak level of

CK-MB is "determined," thereby making the measurement of the "peak level" of CK-MB in the blood sample a positive step.

3. The following represents a new ground of rejection necessitated by Applicant's amendment filed March 29, 2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "significant" in claim 1 is a relative term that renders the claim indefinite. The term "significant" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant asserts that the amendment is supported at page 10, lines 1-5 of the specification as originally filed. However, the specification does not define the metes and bounds of the term. Accordingly, the artisan would not know how much of a decrease in the incidence of myocardial infarctions would constitute a "significant" decrease.

Conclusion

5. No claim is allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
June 20, 2007

DAVID A. SAUNDERS
PRIMARY EXAMINER